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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/837,992	04/18/2001	Hui Tian	18781-006020	8880

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EXAMINER
FRONDA, CHRISTIAN L

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 02/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/837,992	Tian et al.
Examiner	**Art Unit**
Christian L. Fronda	1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-74* is/are pending in the application.

4a) Of the above, claim(s) *19-30 and 33-74* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-18, 31, and 32* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 7
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group I and SEQ ID NO: 3 in Paper No.10 is acknowledged. The traversal is on the grounds that there would be no substantial burden to search all the inventions of Groups I-IX. This is not found persuasive because A search of all the inventions in the patent literature and the non-patent literature cannot be made without serious burden because the inventions require separate searches that have different limits, boundaries, scope, and subject matter as indicated by their different classifications. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their divergent subject matter, restriction for examination purposes is proper..

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-18, 31 and 32, SEQ ID NO: 3 and SEQ ID NO: 4 are under consideration in this Office Action.

Claim Objections

3. Claims 1-18, 31, and 32 are objected to because of the following informalities: Claims 1-18, 31, and 32 are objected to because they recite non-elected subject matter, specifically, SEQ ID NO: 1 and SEQ ID NO: 2. Applicant is required to cancel the claims or amend the claims to recite the elected subject matter of SEQ ID NO: 3 and SEQ ID NO: 4.

Claim Rejections - 35 U.S.C. § 101

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 1-18, 31, and 32 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible asserted utility or a well established utility.

Applicants disclose the nucleotide sequence of SEQ ID NO: 4 and the deduced amino

acid sequence of the protein encoded as SEQ ID NO: 3. Applicants disclose that the protein of SEQ ID NO: 3 is a "SSG polypeptide" which is a generic asserted utility. The specification does not specifically demonstrate the specific function of the protein of SEQ ID NO: 3 or its relationship to any disease. It appears that the main utility of the nucleic acid and protein is to carry out further research to identify the biological function and possible diseases associated with the protein. Substantial utility defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utility. Thus, the claimed invention has no specific or substantial asserted utility.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-18, 31 and 32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to any isolated nucleic acid encoding any SSG polypeptide comprising any amino acid sequence that is at least 70% identical to SEQ ID NO: 3, any isolated nucleic acid comprising a nucleotide sequence at least about 70% identical to SEQ ID NO: 4, or any nucleic acid which hybridizes under moderately stringent or stringent hybridization conditions to SEQ ID NO: 4. The specification, however, only provides the following representative species encompassed by these claims: a polynucleotide consisting of a nucleotide sequence of SEQ ID NO: 4 and a polynucleotide encoding a protein consisting of the amino acid sequence of SEQ ID NO: 3. There is no disclosure of any particular structure to function/activity relationship in the single disclosed species. The specification also fails to describe additional representative species of these polynucleotides by any identifying structural characteristics or properties for which no predictability of structure is apparent. Given this lack of additional representative species as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

8. Claims 1-18, 31, and 32 are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible asserted utility or a well established utility for the reasons set forth above in the rejection of claims 1-18, 31, and 32 under 35 U.S.C. 101, one skilled in the art clearly would not know how to use the claimed invention.

Furthermore, the claims encompass any isolated nucleic acid encoding any SSG polypeptide comprising any amino acid sequence that is at least 70% identical to SEQ ID NO: 3, any isolated nucleic acid comprising a nucleotide sequence at least about 70% identical to SEQ ID NO: 4, or any nucleic acid which hybridizes under moderately stringent or stringent hybridization conditions to SEQ ID NO: 4 which is not enabled by the specification.

Factors to be considered in determining whether undue experimentation is required, are summarized In re Wands [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

While molecular biological techniques and genetic manipulation techniques are known in the prior art and the skill of the artisan are well developed, knowledge regarding the biological function, biological activity, or utility of any isolated nucleic acid encoding any SSG polypeptide comprising any amino acid sequence that is at least 70% identical to SEQ ID NO: 3, any isolated nucleic acid comprising a nucleotide sequence at least about 70% identical to SEQ ID NO: 4, or any nucleic acid which hybridizes under moderately stringent or stringent hybridization conditions to SEQ ID NO: 4 is lacking. Thus, searching for the biological function, biological activity, or utility of said polynucleotides is well outside the realm of routine experimentation and predictability in the art of success in determining the biological function, biological activity, or utility of said polynucleotides is extremely low.

The amount of experimentation to determine the biological function, biological activity, or utility of said polynucleotide is enormous and entails searching for any biological source which contains the said polynucleotides, genetically modify the nucleotide sequence by deletion, insertion, substitution, or combinations thereof of nucleotides at any position to make a nucleotide sequence at least about 70% identical to SEQ ID NO: 4 and searching for a specific biological function, biological activity, or utility of the polynucleotide. Since routine experimentation in the art does not include such undue experimentation, where the expectation of obtaining a desired biological function, biological activity, or utility is unpredictable, the Examiner finds that one skilled in the art would require additional guidance, such as information regarding the structure and function relationship of the claimed polynucleotides. Without such a guidance, the experimentation left to those skilled in the art is undue.

Claim Rejections - 35 U.S.C. § 112, 2nd Paragraph

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claim 1-18, 31, and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, the phrase "encoding an SSG polypeptide" renders the claim vague and indefinite because the specific protein or enzyme encoded by the claimed nucleic acid is not known and not recited and the specific function of the "SSG polypeptide" is not known and not recited. Claims 2-18, 31, and 32 which depend from claim 1 are also rejected because they do not correct the defect of claim 1.

In claim 2, the phrase "said polypeptide specifically binds to polyclonal antibodies" renders the claim vague and indefinite because the specific structure and amino acid sequence of the claimed polyclonal antibodies are not known and not defined.

In claim 4, the phrase "ABC polypeptide, and wherein said dimer exhibits sterol transport activity" renders the claim vague and indefinite" renders the claim vague and indefinite because the specific structure and identity of the claimed "ABC polypeptide" is not known and not recited in the claim. Claims 5-7 which depend from claim 4 are also rejected because they do not correct the defect of claim 4.

Claim 7 is vague and indefinite because the meaning of the word "ABC8" is not known and not recited in the claim. Reciting the full name of the acronym may overcome this rejection.

Claim 8 is vague and indefinite since the specific conditions for the "moderately stringent hybridization conditions" are not known and not recited in the claim.

Claim 9 is vague and indefinite since the specific conditions for the "stringent hybridization conditions" are not known and not recited in the claim.

In claim 14, the phrase "LXR agonist" renders the claim vague and indefinite because the specific structure and identity of the claimed "LXR agonist" is not known and not recited in the claim.

Conclusion

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (703)305-1252. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703)308-3804. The fax phone number for this Group is (703)308-0294. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703)308-0196.

CLF